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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,622	BACHYNSKY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *15-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 54* is/are rejected.

7)☒ Claim(s) *54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-54 are presented for examination.

Acknowledgement is made of the present application as a proper National Stage (371) entry of PCT Application No. PCT/US99/16940 filed July 27, 1999, which claims priority under 35 U.S.C. 119(e) to United States Provisional Patent Application No. 60/094,286, filed July 27, 1998. Applicant's "Response to Restriction/Election Requirement" filed November 8, 2004 has been received and entered into the application.

Election/Restriction Requirement

Applicant's election without traverse of Group I (claims 1-14 and 54) and election of 2,4-dinitrophenol as the mitochondrial uncoupling agent and glucagon as the second therapeutic agent in the reply filed on November 8, 2004 is acknowledged. Applicant has identified the following claims as reading on at least one of the elected species: claims 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14 and 54. The Examiner has noted that each of claims 1-14 and 54 reads on at least one of the elected species. Claim 12 is considered to read on the elected species of glucagon, insofar as glucagon is considered to meet the limitation of "various hormones" as recited at page 101, line 16 of the claim.

Therefore, for the reasons set forth above and of record at pages 2-4 of the previous Office Action dated October 6, 2004, the restriction requirement is still deemed proper and is therefore made **FINAL**.

Claims 15-53 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

The claims corresponding to the elected subject matter are 1-14 and 54 and such claims are herein acted on the merits to the extent they read on the elected subject matter identified above.

Claim Objection

Claim 54 is objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit, either physically or materially, the subject matter of the method recited in previous claim 1. The recitation of "wherein the uncoupling agent is produced using combinatorial technology" is merely a statement that further defines the agent by the process by which it was produced, but does not impart any physical or otherwise material property to the agent that is not already present in the method using the agent as recited in present claim 1. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Specification

Applicant's "Cross-Reference to Related Applications" at line 8 of page 1 of the specification has been noted by the Examiner to be incomplete. Applicant has merely stated the priority claim under 35 U.S.C. 119(e) to provisional application number 60/094,286 filed July 27, 1998, but has omitted reference to PCT Application No. PCT/US99/16940, filed July 27,

1999, of which the present application is a proper National Stage (371) entry. Appropriate correction to the specification is required.

The disclosure is objected to for providing a description of "Figure 17a" at page 18, line 2 of the disclosure with no such corresponding figure present in the submitted set of drawings. Appropriate correction to the specification or the submission of new Figure 17a is required. If a new figure is submitted, each new drawing must be in compliance with 37 C.F.R. 1.121(d) and each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 C.F.R. 1.121(d).

A description of Figures 8a and 8b and Figure 21, parts 1, 2 and 3, has not been provided in the present disclosure at pages 17-18 of the specification under the section entitled "Brief Description of the Drawings". Applicant is required to have a description of each figure and sub-figure in the disclosure (see MPEP §608.01(f)). Appropriate correction to the specification is required.

The Examiner has noted that reference numbers 238-241 under the section entitled "REFERENCES" are missing from the disclosure at page 90. Appropriate correction is required.

The use of the trademark ORGANETICS PSI® has been noted in this application. Each letter of the trademark should be capitalized wherever it appears, be accompanied by the generic terminology and by the appropriate symbol designating trademark (e.g., ® or ^{TM}). Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

The disclosure is objected to because of the following minor informalities:

(i) the word "were" at line 24 of page 4 and at line 26 of page 19 of the disclosure should be changed to "where" for clarity; and

(ii) the word "pyruvate" is misspelled at line 7 of page 25 of the disclosure.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-14 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of Non-Hodgkin's lymphoma, prostate carcinoma, glioblastoma multiforme or Kaposi's sarcoma (see the present specification at page 14, lines 31-34), infections that result from Borrelia burgdorferi, Mycobacterium leprae, Treponema pallidum, HIV, hepatitis C, herpes virus or papillomavirus (see the present specification at page 14, line 34-page 15, line 2), or infestations that result from Candida, Sporothrix schenkii, Histoplasma, Paracoccidiodes, Aspergillus, Leishmania, malaria, acanthomoeba or cestodes (see the present specification at page 15, lines 2-4), does not reasonably provide enablement for the treatment of malignancies, i.e., cancer in general, infections in general, infestations in general or all other medical conditions (as recited in claim 5 by the recitation "other medical conditions") as is encompassed in claims 5-7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with this claim.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988). The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The breadth of the claims has also been considered and is discussed below.

The present claims are directed towards a method of treating cancer, infections, infestations and "other medical conditions" in general using a mitochondrial uncoupling agent, such as 2,4-dinitrophenol, in order to induce intracellular hyperthermia. The claims are broad in that they encompass the treatment of all cancer types, infection types or infestation types in general, as well as all other medical conditions in general. While the Examiner has considered the present claims in light of the accompanying specification, it is noted that the present disclosure is lacking sufficient enablement to support or to be commensurate in scope with the claimed subject matter.

The present specification is evaluated by the Examiner as directed by the Court in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient

reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement in claims 5-7 that cancer in general may be treated is doubted because, while the state of the art of cancer treatment is well developed with regard to the treatment of specific cancer types (see the Cecil reference newly cited by the Examiner at pages 1060-74), the state of the art with regard to treating cancer broadly is underdeveloped, despite the fact that the level of skill in the art is high, e.g., at least that of a physician with several years of experience. In particular, there is no known anticancer agent or combination of anticancer agents that is effective against all cancer types. The Cecil reference clearly shows that for the various known cancer types, there is not one specific chemotherapeutic agent or combination thereof that is effective for each and every type of cancer (see page Table 198-5 at page 1065; Tables 198-6 and 198-7 at page 1066; Table 198-8 at page 1068; and Table 198-9 at page 1071). In light of the fact that there is no one particular agent or combination of agents known to be effective for the treatment of cancer/tumors in general, the mere recitation of "cancer" is insufficient to enable one of ordinary skill in the art to practice the instant invention with regard to cancer. In order for the skilled artisan to practice the treatment of cancer in general, there would be placed on said artisan an undue burden of determining which types of cancer, other than Non-Hodgkin's lymphoma, prostate carcinoma, glioblastoma multiforme or Kaposi's sarcoma as described in the present specification at page 14, lines 31-34 and in Examples 4 (page 47, line 17-page 49, line 11), 7-9 (page 51, line 5-page 59, line 25) and 11 (page 62, line 25–page 63, line 23), would be amenable to treatment with the claimed active agent(s).

Furthermore, the objective truth of the statement in claims 5-7 that infections or infestations in general may be treated is also doubted because, while the state of the art of infection or infestation treatment is well developed with regard to the treatment of specific types of infection or infestation (see Cecil's, p.1591-1603 and 1858-1888), the state of the art with regard to treating either infection or infestation broadly is underdeveloped, despite the fact that the level of skill in the art is high, e.g., at least that of a physician with several years of experience. In particular, there is no known agent or combination of agents that is effective against all types of infection or infestation. The Cecil reference clearly shows that for the various types of infection or infestation, there is not one specific therapeutic agent or combination thereof that is effective for each and every type of infection or infestation (see Cecil's, Table 318-6 at page 1600, and the inset boxes of each specific type of fungus at pages 1858-1888). In light of the fact that there is no one particular agent or combination of agents known to be effective for the treatment of infections or infestations in general, the mere recitation of the term "infections" or "infestations" is insufficient to enable one of ordinary skill in the art to practice the instant invention with regard to infections or infestations in general. In order for the skilled artisan to practice the treatment of infections or infestations in general, there would be placed on said artisan an undue burden of determining which types of infections or infestations, other than those resulting from Borrelia burgdorferi, Mycobacterium leprae, Treponema pallidum, HIV, hepatitis C, herpes virus, papillomavirus, Candida, Sporothrix schenkii, Histoplasma, Paracoccidiodes, Aspergillus, Leishmania, malaria, acanthomoeba or cestodes as described in the present specification at page 14, line 34-page 15, line 4, would be amenable to treatment with the claimed active agent(s).

Lastly, the objective truth of the statement that "other medical conditions" may be diagnosed or treated as recited in present claim 5 is doubted because the claim encompasses the improvement of *any and all* medical conditions, including any and all disease states, and such reads on the claimed active mitochondrial uncoupling agent acting as a panacea.

While the Examiner cannot locate a reference teaching expressly that a panacea does not exist, the following references are relied upon in support of the Examiner's position: Kumar (cited by the Examiner, reference "U" on the attached form PTO-892) teaches, "The role of melatonin in organisms physiology has now been widely recognized, and the wealth of information accumulated in the past two decades indicate it to be the best hormone candidate to be investigated for a universal panacea." (penultimate and last line of the abstract); Oka et al. (cited by the Examiner, reference "V" on the attached form PTO-892) teaches "At the present time, however, there is no single panacea. To achieve the maximum preventive and therapeutic effects with the minimum toxicity, two or more immunosuppressive drugs are used appropriately in combination, taking the mechanisms of action of each into consideration (penultimate and last line of the abstract); Smith et al. (cited by the Examiner, reference "W" on the attached form PTO-892) teaches "[hormone replacement therapy] is not a panacea for an unhealthy lifestyle." (line 11 of the abstract); and Rickels et al. (cited by the Examiner, reference "X" on the attached form PTO-892) teaches "Anxiolytics are not a panacea, but only tools to allow the patient to help himself or herself." (lines 11-12 of the abstract).

The art is currently unaware of any compound or combination of compounds that may be used to treat any and all diseases in a host and lacking such knowledge, the skilled artisan would

be faced with the impermissible burden of undue experimentation in attempting to practice the present invention in a manner commensurate in scope with present claim 5.

Thus, for the above reasons, claims 5-14 and 54 are deemed properly rejected.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The term "analog" in claim 13 and the term "derivative" in claim 14 are relative terms that render the claims indefinite. In particular, "analog" does not particularly point out the degree of similarity to the original compound, 2,4-dinitrophenol. Similarly, the term "derivative" does not particularly point out the degree or type of derivation that a given compound may have in relation to the parent compound and still be considered a "derivative" as intended by Applicant. Applicant has failed to provide any specific definition for these terms in the present specification. Lacking a clear meaning of the terms "analog" or "derivative", the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection.

In the present specification at page 27, lines 19-20, Applicant has set forth:

> "Various conjugates, adducts, analogs and derivatives of the above mentioned agents can be formulated and synthesized to enhance intracellular uncoupling and heat production."

Such disclosure, however, does not render the claims definite. Words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision" (MPEP §2111.01). Here, Applicants' definition of "analog" or "derivative"' is not reasonably clear, deliberate or precise because the mere statement of the use of an analog or a derivative does not specify what other compounds may be considered 2,4-dinitrophenol analogs or derivatives. That is, the definitions are presented in a non-limiting manner. Thus, the identity of those compounds that are included or excluded by the term "analog" or the term "derivative" is open to subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C. §112, second paragraph.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). In order to anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q.1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). In order to inherently anticipate, the prior art must

necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile,* 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubin (U.S. Patent No. 4,481,195; 1984).

Rubin teaches a method of treating malignant tumors exhibiting β-glucuronidase activity by employing a glucuronide compound with toxic aglycones, of which the method is selectively toxic to tumor cells, but does not harm healthy tissue (col.1, lines 18-23 and col.2, lines 30-51). Rubin also teaches that the method may be useful in treating bacterial cells that also exhibit high β-glucuronidase activity, such as streptococcus, staphylococcus or *E.coli* (see abstract, for example, col.2, lines 48-51, or col.5, lines 1-8). Rubin further teaches that the β-glucuronidase activity of the tumor cells may be increased by methods such as elevating the temperature of the toxic cells at the time of treatment by using a pyrogenic drug, such as dinitrophenol, an especially preferred glucuronide compound (col.3, lines 34-40 and 46-51), or a conjugate of

dinitrophenol such as 2,4-dinitrophenol-β-D-glucuronic acid (see claim 3, col.9, lines 44-46), in order to make the cells more susceptible to the toxic effects of the aglycones components of the glucuronide compound. Rubin expressly discloses that, "local hyperthermia in the region of suspected tumor cells is preferred to general hyperthermia because general hyperthermia will also increase the β-glucuronidase activity in healthy cells" (col.3, lines 57-60).

Rubin's disclosed method of administration of glucuronide therapy for the treatment of malignant tumor cells exhibiting high levels of β-glucuronidase activity must also be accompanied by a hyperacidification of the tumor cells, in order to enhance β-glucuronidase activity in the tumor cells (col.3, lines 11-17). Rubin expressly teaches that this may be achieved through the administration of an additional agent that induces hyperglycemia, such as fructose, galactose, lactose or glucagon, or in the case of a diabetic patient, decreasing the amount of insulin administered (col.6, lines 60-68). In order to decrease or eliminate β-glucuronidase activity in healthy tissues, such as the kidneys, spleen and liver, and, thus, less susceptible to the toxic effects of the aglycones, Rubin teaches the administration of an alkalinizing agent prior to or simultaneously with the glucuronide compound (col.2, line 56-col.3, line 1).

Rubin teaches that, "It is clear that any tumor cells have β-glucuronidase activity may be treatable in accordance with the present invention with the remaining organs of the body being protected by the alkalinization step. Tumors which are known to have β-glucuronidase activity include solid breast tumors and their metastases, bronchogenic carcinoma and its metastases, and lymphomas...It must be understood, however, that this list is not meant to be complete, and that the prior art is aware of many other tumors that have β-glucuronidase activity" (col.7, lines 34-47).

Although Rubin expressly discloses dinitrophenol and 2,4-dinitrophenol-β-d-glucuronic acid, the reference does not expressly disclose **2,4-dinitrophenol** alone. Because the reference discloses the genus of compounds known generally as dinitrophenol and the number of species (e.g., 2,4-dinitrophenol, 2,5-dinitrophenol or 2,6-dinitrophenol; See The Merck Index, 11th Edition, 1989; p.518, Monographs 3274-3276) is sufficiently small, the teachings of Rubin places the use of 2,4-dinitrophenol well within the possession of the public and the reference is, thus, considered to anticipate this limitation. The claims are, therefore, properly rejected under 35 U.S.C. 102(b). See *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978). See MPEP §2131.02 and §2144.08 for more information on anticipation and obviousness of species by a disclosure of a genus.

Rubin discloses the use of 2,4-dinitrophenol-β-d-glucuronic acid in claim 3 (see col.9, lines 44-46). It is apparent that such is considered to be a conjugate of the pyrogenic agent 2,4-dinitrophenol with glucuronic acid according to the disclosure of Rubin at col.1, lines 26-30. In light of the fact that Applicant has failed to provide sufficient guidance in the present specification or claims disclosing the degree of similarity to the parent compound (2,4-dinitrophenol) to be considered an "analog" or the degree or type of derivation that a given compound may have in relation to the parent compound and still be considered a "derivative" as intended by Applicant (see above, under "Claim Rejection-35 U.S.C. 112, Second Paragraph"), the Examiner has considered the disclosed compound 2,4-dinitrophenol-β-d-glucuronic acid as taught in claim 3 of Rubin to meet Applicant's limitation of "an analog of 2,4-dinitrophenol" as recited in present claim 13 or "a derivative of 2,4-dinitrophenol" as recited in present claim 14.

The Examiner has noted the recitation of the limitation "...wherein the uncoupling agent

is produced using combinatorial technology" (claim 54, page 112, line 14) in present claim 54, but such a recitation is merely a statement that further defines the active uncoupling agent by the process from which it was produced. Such is not considered to impart any physical or otherwise material feature to the agent that is not already found in the agent employed in the method of the prior art of Rubin, nor is it considered to further limit the agent used in the method of present claim 1 (see above, "Claim Objection"). The Examiner has noted that if a method using an active agent or combination of active agents is itself anticipated by the prior art, then any recitation of the process by which the active agent is made is merely a *statement* of the same, but such fails to alter the constitution of the active agent itself and, therefore, has no impact on the practice of the method. In the absence of any physical or material difference, the active agent used in the method of the present claims is still fundamentally equivalent to the active agent used in the method taught by the prior art. In light of the disclosure of Rubin, which directly anticipates the method of present claims 1-14 and 54, such claims are deemed properly rejected under 35 U.S.C. 102(b).

Rejection of Claims 8 and 10 Based on Inherency

It is recognized that the prior art teachings of Rubin do not expressly recite that the administration of a second medication, such as glucagon, in combination with a mitochondrial uncoupling agent, will "increase the overall metabolic rate of the animal, the metabolic rate of a specific target tissue in the animal, or an increase in free radical flux" as recited in present claim 8, nor does the reference recite that the induced intracellular hyperthermia involves "the induction of heat shock proteins" as recited in present claim 10. The reference does, however,

teach a method of treating tumor or bacterial cells exhibiting high β-glucuronidase activity by inducing local hyperthermia using a pyrogenic drug such as dinitrophenol in combination with a second medication, such as glucagon, for hyperacidification of the target cells (see col.2, line 56-col.6, line 68 of Rubin). However, because the particular method steps and compounds that are present in the instant claims are also in the patent, it is deemed that the increase in metabolic rate of the animal or target tissue, the increase in free radical flux, or the induction of heat shock proteins resulting from induced intracellular hyperthermia would have been inherent in the method disclosed by the prior art of Rubin, whether recognized by the patentee or not. The claiming of a new use, new function or **unknown property** that is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 U.S.P.Q. 430, 433 (CCPA 1977). See also MPEP §2112. It is irrelevant that the prior art observer did not recognize the property or function of the disputed claims; if the prior art inherently possesses that characteristic, it anticipates. Applicant's attention is further drawn to the MPEP at §2113, which states, "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Thus, claims 8 and 10 are properly rejected as being inherent and anticipated by Rubin.

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent Nos. 4,337,760 (Rubin; 1982), 5,005,588 (Rubin; 1991), 5,240,914 (Rubin; 1993), 5,340,803 (Rubin; 1994), 5,476,842 (Rubin; 1995), 5,639,737 (Rubin; 1997) and 5,760,008 (Rubin; 1998).

Rejection of claims 1-14 and 54 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The Examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

April 8, 2005

RAYMOND HENLEY III
PRIMARY EXAMINER
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